UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,501	04/16/2001	Tyler B. Parr		5399

7590 05/20/2003

Tyler Parr, Ph.D.
P.O. Box 371
Chula Vista, CA 91912

EXAMINER	
JOYNES, ROBERT M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/835,501	PARR, TYLER B.	
	Examin r	Art Unit	
	Robert M. Joynes	1615	

-- Th MAILING DATE of this communication appears on th cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☒ Claim(s) *2-4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment and Response filed on December 23, 2003

Claim Objections

Claims 2-4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 is drawn to a method whereas Claims 2 and 3 are drawn to the individual components and Claim 4 is drawn to a dosage form. Claims 2-4 fail to further limit the method of Claim 1. It is suggested that the claims be amended to reflect that they depend upon a method claim. For example, Claim 2 can begin as follows: The method of Claim 1 wherein component 1 is a substance selected from the group consisting of [enter Markush group here].

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for augmenting the release of growth hormones, does not reasonably provide enablement for augmenting the all the biological systems recited, such as the neurological system or the immune system. The specification does

not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)), the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation; (b) the amount of guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the predictability of the prior art; (g) the breadth of the claims; and (h) the relative skill in the art.

(a) In order to utilize the system as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. An undetermined number of experimental factors utilizing a system for all of the treatments of condition and disorders recited in instant Claim 6 would have to be resolved by the practitioner for the reasons discussed below.

(b & c) The specification states that objects of the invention include providing a system (and method) for augmenting the release of growth hormone in vertebrates (See page 7, Summery, Object and Advantages), and outlines a set of generic means/steps for implemented by the system, wherein the a composition comprising acetyl-l-carnitine and l-ornithine is administered. However, the specification lacks a reasonable level of guidance for a system/method for said method augmenting various systems and/or conditions such as the immune system or the circadian rhythm entraining system, and working and/or prophetic examples are clearly absent. Applicant has not taught or

defined how the invention arrives at a means for augmenting such systems. There is no guidance as how this composition effects or augments such system in the body, nor any substantial teachings as to which system is effected at what dosage with each other.

(d) The nature of augmenting various biological systems that do not appear to have a common characteristic that would link the system activity of one to the other, is complex.

(e & f) Although the art provides a certain level of guidance with regards to the use of acetyl-l-carnitine and l-ornithine as dietary supplements, these teachings do not provide sufficient guidance where the specification is lacking. The art demonstrates that the effect these amino acids have on the body is clearly not predictable. Gardiner teaches that strenuous exercise cause muscle to urn up a portion of its protein structure but the reason for this is unclear (See Col. 2, lines 30-40). This demonstrated while one system can be effected by the administration of certain compounds such as amino acids, either systems may or may not be effected by the same compounds. Only through experimentation can the effects on various biological systems be determined.

(g) The claims are broad because there is no guidance for the appropriate amounts of each substance that would have a beneficial effect on each biological system listed.

(h) The level of skill of those in the art involving the optimization of these substance on each biological system recited is high.

The skilled practitioner would first turn to the instant specification for guidance in augmenting every system recited in the instant claims. However, the specification does

not provide sufficient guidance for augmenting every biological system recited in the instant claims. As such, the skilled practitioner would turn to the prior art for such guidance. However, the prior art does not teach how acetyl-l-carnitine and l-ornithine affect every biological system recited in the instant claims. Finally, said practitioner would turn to trial and error experimentation to make/use a composition comprising acetyl-l-carnitine and l-ornithine to augment the various biological systems, without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the method of augmentation is actually perform or how the composition is administered. The Claim fails to set forth any method step to properly define the method. Recitation of a step in the method is suggested.

Claims 2-4 are indefinite because the claims must be set forth as complete sentences. MPEP 608.01(m). It is suggested that the claims be amended as suggested in the Claim Objections set forth above in this Office Action to form complete sentences.

Claims 5, 7 and 8 are rejected as being indefinite because they recite the term "fast" and define it as a 3 to 4 hour period. This time period does not appear to be a

fast, abstention from food. The period of 3 to 4 hours is the normal time frame for food to be processed in the gastrointestinal tract after ingestion of food. Therefore, it is unclear how 3 to 4 hours can be a fasting.

Claim 7 recites the limitation "the preferred night time human pharmacological dose" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. In no claim prior to Claim 7 is the dosage described as a night time dosage.

Claims 9 and 10 are rejected for depending upon indefinite parent claims. Being that all the limitations of the parent claims are to be read into the dependent claims, they too are rendered indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Gardiner (US 5817329). Gardiner teaches a dietary supplements comprising acetyl-L-carnitine and L-leucine, L-valine, L-mrthionine, L-arginine and ornithine (Col. 6-10, Claims 1-18). The dietary supplement is to be used by bodybuilders and athletes (Col. 4, lines 39-51). The acetyl-L-carnitine is present in the dietary supplement from about 500 mg to about 1500 mg (Col. 6, Claim 1). The additional amino acids that are included are present from about 400 mg to about 600 mg (Col. 8, Claim 11).

Claim Rej ctions - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardiner. The teachings of Gardiner are discussed above. Gardiner does not expressly teach the exact concentration ranges of components 1 and 2.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amount of components 1 and 2 in the dietary supplement

One of ordinary skill in the art would have been motivated to do this to prepare various dosage levels for the different types of subjects ingesting the supplement, i.e., once daily dosages as opposed to multiple dosages or differing dosages for different conditions treated.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed November 28, 2002 have been fully considered but they are not persuasive. Applicant argues that the prior art does not teach a method of augmenting growth hormone release.

It is the position of the Examiner that the prior art teaches the same or similar composition containing acetyl-l-carnitine and orthinine that is administered as a dietary supplement to help build muscle during training. It is therefore the same underlying method of administering a composition of acetyl-l-carnitine and orthinine to achieve the same basic result of building tissue in the body. Finding the mechanism by which that composition works in doing so does not impart patentability. Therefore, the instant claims are anticipated by the Gardiner reference.

An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

Applicant is advised of the availability of the publication "Attorneys and Agents Registered to Practice Before the U.S. Patent and Trademark Office." This publication

is for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Applicant can also contact Customer Service for a listing of registered attorneys or agents in their geographical location.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims

appealed. The Notice of Appeal must be accompanied by the required appeal fee of $320.00 or $160.00 for small entity status.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone

numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
May 16, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600